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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/525,640	02/25/2005	Krister Henriksson	06275-442US1 100604-1P US	9646
26164	7590	01/23/2006	EXAMINER	
FISH & RICHARDSON P.C. P.O BOX 1022 MINNEAPOLIS, MN 55440-1022			KOSACK, JOSEPH R	
			ART UNIT	PAPER NUMBER
			1626	
DATE MAILED: 01/23/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/525,640

Applicant(s)

HENRIKSSON ET AL.

Examiner

Joseph Kosack

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 February 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-14 and 18-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-14 and 18-20 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### DETAILED ACTION

Claims 1-14 and 18-20 are pending in the instant application.

#### *Election/Restrictions*

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Due to the numerous variables in the claims, e.g. R<sup>1</sup>, R<sup>2</sup>, R<sup>3</sup>, R<sup>4</sup>, etc... and their widely divergent meanings, a precise listing of inventive groups cannot be made. The following groups are exemplary:

Group I, claim(s) 1-11 (in part) and 13 (in part), drawn to compounds of Formula I and their pharmaceutical composition wherein the compound is 2-(2,5-dioxoimidazolidin-4-yl)-N-[2-(4'-fluoro-biphenyl-4-yl)-ethyl]-acetamide.

Group II, claim(s) 1-11 (in part) and 13 (in part), drawn to compounds of Formula I and their pharmaceutical composition wherein the compound is N-(2-biphenyl-4-yl-ethyl)-2-(2,5-dioxoimidazolidin-4-yl)-acetamide.

Group III, claim(s) 1-11 (in part) and 13 (in part), drawn to compounds of Formula I and their pharmaceutical composition wherein the compound is N-[2-(4'-benzyloxy-biphenyl-4-yl)-ethyl]-2-(2,5-dioxoimidazolidin-4-yl)-acetamide.

Group IV, claim(s) 1-11 (in part) and 13 (in part), drawn to compounds of Formula I and their pharmaceutical composition wherein the compound is N-[2-(3',5'-dichloro-biphenyl-4-yl)ethyl]-2-(2,5-dioxoimidazolidin-4-yl)-acetamide.

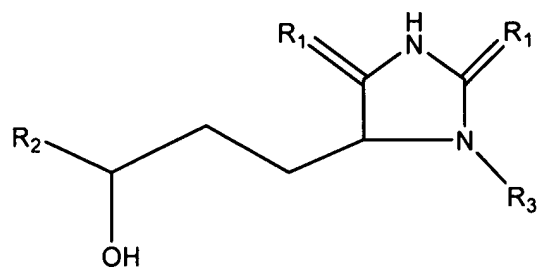
Group V, claim(s) 1-11 (in part) and 13 (in part), drawn to compounds of Formula I and their pharmaceutical composition wherein the compound is 2-(2,5-dioxoimidazolidin-4-yl)-N-[2-(4-pyridin-3-yl-phenyl)ethyl]-acetamide.

Group VI, claim(s) 1-11 (in part) and 13 (in part), drawn to compounds of Formula I and their pharmaceutical composition wherein the compound is 2-(2,5-dioxoimidazolidin-4-yl)-N-[2-(4-furan-2-yl-phenyl)ethyl]-acetamide.

Group VII, claim(s) 12 & 14, drawn to methods of preparation of compounds and compositions of Formula I.

Group VIII, claim(s) 18-20, drawn to methods of use of compounds and compositions of Formula I.

In accordance with 37 CFR 1.499, Applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted. Again, **this list is not exhausted**, as it would be impossible under the time constraints due to the sheer volume of subject matter instantly claimed. Therefore, Applicant may choose to elect a single invention by identifying another specific embodiment not listed in the exemplary groups of the invention and Examiner will endeavor to group the same. **If Applicant is unable to elect a single invention, Applicant may instead choose to elect a specific compound and Examiner will attempt to group it.** The claims herein lack unity of invention under PCT Rule 13.1 and 13.2 since the compounds defined in the claims lack a significant structural element qualifying as the special technical feature that defines a contribution over the prior art. The compounds claimed contain



, where R<sub>1</sub> is S or O, R<sub>2</sub> is C or N, and R<sub>3</sub> is H or methyl, which does not define a contribution over the prior art (see Nicolet, *Journal of the American Chemical Society* 1930, 1192-1195). The substituents vary extensively and when taken as a whole result in vastly different compounds. Accordingly, unity of invention is considered to be lacking and restriction of the invention in accordance with the rules of unity of invention is considered proper. Additionally, the vastness of the claimed subject matter and the complications in understanding the claimed subject matter imposes a burden on any examination of the claimed subject matter. The method of use claims will be examined with the elected invention commensurate in scope therewith.

A telephone call was made to Janis K. Fraser, Ph.D., J.D. on January 17, 2006 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

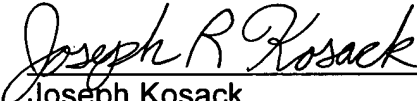
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remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Kosack whose telephone number is (571)-272-5575. The examiner can normally be reached on M-F 7:15-3:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571)-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
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Art Unit 1626

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